JUL 1 1 2000

K001324

V. 510(k) SUMMARY

Safety and effectiveness information concerning this device is summarized below. Because this is not a CLASS III device, the special certification defined in this section is not required.

Submitted by:

Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

Contact Person: David B. Jones

Date Prepared: April 21, 2000

Device Name:

SYNAMPS® (32 - 64 channels)
ESI™ SYNAMPS® (65 - 128 channels)
ESI™ SYNAMPS® (129 - 256 channels)

Common Name:

Electroencephalograph (EEG)
Electromyograph (EMG)
Evoked Response (EP)

Classification Name:

Electroencephalograph (84GWQ)
Electromyograph (89GWP)
Evoked Response Electrical Stimulator (84GWF)
Evoked Response Photic Stimulator (84GWE)
Evoked Response Auditory Stimulator (84GWJ)

Device Classification

Class II: 21 CFR §:		
	882.1400	Electroencephalograph
	890.1375	Electromyograph
	882.1870	Evoked Response Electrical Stimulator
	882.1890	Evoked Response Photic Stimulator
	882.1990	Evoked Response Auditory Stimulator

K001324

Predicate Device(s)	510(k)	Name
Axon Systems Neurological Work Station:	K971819	Epoch 2000
Bio-Logic 128-Channel Recording System:	K973883	Ceegraph
Biosound Esoate	K970703	Galileo
Nicolet Biomedical Multi-Modality System:	K991054	Bravo
Nihon Kohden MEB-2200A:	K991899	Neuropack
Nihon Kohden EEG-1100A:	K992742	Neurofax

Device Description and Summary of Technological Characteristics:

The Neurosoft SYNAMPS® is a software-programmable 32 channel amplifier capable of direct current (DC) or alternating current (AC) recordings, including signal amplification, analog-to-digital conversion, filtering, and the transfer that data to a host computer. SYNAMPS® permits high-speed simultaneous sampling and acquisition via an onboard computer and flash disk without burdening the host computer that is controlling, displaying, or storing the acquired data. SYNAMPS®'s software routines separately control each channel and perform real-time digital filtering.

SYNAMPS®'s first stage amplification takes place at the head box reducing noise pickup. Each 32-channel unit can be configured for any number of bipolar or monopolar channels and a connector is available for electrode cap array applications. SYNAMPS® was designed as a stand-alone-unit and so multiple units can be interconnected together to provide synchronized data acquisition for up to 256 channels. Neurosoft's Electric Source Imaging (ESI™) measures and analyzes EEG/EP/ERP signals and performs analysis of complete data sets, makes statistical comparisons between individuals or groups, and presents results as annotated signal plots or topographic/tomographic maps in a realistic three-dimensional (3-D) context. SYNAMPS® is optically isolated and transformers are available for line voltages of 100, 120, 230 VAC.

SYNAMPS®'s features simplify the acquisition, recording and analysis of neurophysiology imaging. ESI™ allows users to "touch button" calibrate the acquisition system and to view a topographic display of each channel's impedance. ESI™ also permits selection of on-line display of continuous data from a user defined channel, subsets or all channels at the same time, and includes raw unaveraged data epochs, multiple average "bins" and FFT histograms. SYNAMPS®'s "Off-Line Analysis" includes basic and advanced features, including:

- artifact removal,
- zero-phase-shift filtering,
- time and frequency domain signal averaging,
- statistical comparisons between individuals and groups.
- event-related synchronization/desynchronization,
- event-related coherence,
- spatial principal component analysis, and
- Scalp current density (Laplacian).

The Neurosoft SYNAMPS® systems works in the same manner as each of the approved and predicate devices, and:

- permits 8, 16, 24 or 32 channel configurations,
- allows for multiple 32-channel systems for high-resolution 128/256 channel systems, and
- simplifies the acquisition, recording and analysis of the data generated in high-resolution.

Indications For Use:

The Neurosoft SYNAMPS® systems is intended for the measuring, recording and analysis of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EEG/EMG/EP.

Patient Population:

Adults, children and infants.

Summary of Non-Clinical Testing:

The following is a list of tests performed on the Neurosoft SYNAMPS® EEG/EMG/EP system. These tests demonstrate that the performance of the system is equivalent to that of the predicate devices in the terms of safety and effectiveness, and that the additional features provide utility and product performance which exceeds that of the predicate devices. All tests were completed satisfactorily without adverse report.

The Neurosoft SYNAMPS® EEG/EMG/EP system was designed, and is manufactured and tested to comply with:

- IEC-60601-1,
- IEC-60601-1-1,
- IEC-60601-1-1-2,
- IEC-60601-1-1-4,
- IEC-60601-1-2-26,
- EN ISO 9001,
- EN 46001,
- MDD 93/42/EEC,
- AAMI EC53-1995, and
- CDRH Guidance Document on the "Performance Standard for Electrode Lead Wires and Patient Cables," March 9, 1998.

Summary of Complaints:

Neurosoft is not aware of any MDR reportable event, or any other reported incidence where a user or patient has been exposed to extraneous electrical current.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2000

Mr. David B. Jones
Regulatory Affairs and
Quality Assurance Manager
Neurosoft, Inc.
5700 Cromo Drive
El Paso, Texas 79912

Re: K001324
Trade Name: Synamps® System
Regulatory Class: II
Product Code: GWQ, GWP, GWF, GWE, GWJ
Dated: April 21, 2000
Received: April 26, 2000

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Statement of Indications for Use

Applicant: Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

510(k) Number: K001324

Device Name: Neurosoft **SYNAMPS®** system

Indications For Use: The Neurosoft **SYNAMPS®** system is intended for the measuring, recording and analysis of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EEG/EMG/EP.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001324